

Robert Shull, M.D.

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

Master File No. 2:12-MD-02327
MDL 2327

JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE

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IN RE: ETHICON, INC. PELVIC §
REPAIR SYSTEM PRODUCTS §
LIABILITY LITIGATION §

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Ana Ruebel v. Ethicon, Inc. et al. §
Civil Case No. 2:12cv00663 §

Harriet Beach v. Ethicon, Inc. et al. §
Civil Case No. 2:12cv00476 §

Carol Jean Dimock v. Ethicon, Inc. et al. §
Civil Case No. 2:12cv00401 §

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- - -
MARCH 10, 2016
- - -

Video deposition of Robert Shull, M.D.,
held at Beck Redden, LLP, 515 Congress,
Suite 1900, Austin, Texas 78701, commencing
at 9:54 a.m., digitally recorded at the date
and time aforesaid and transcribed by
Danielle Coleman, Court Reporter.

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11 Also present:

12 PETER ZIERLIEN, VIDEOGRAPHER

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Testimony of: ROBERT SHULL, M.D.

PAGE

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DIRECT EXAMINATION BY MS. VAN STEENBURGH.....

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E X H I B I T S

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DEPOSITION

PAGE

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EXHIBIT NO. 1

NOTICE OF TAKING DEPOSITION

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(Retained by Ms. Van Steenburgh)

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1 THE VIDEOGRAPHER: We are now on the record.
2 My name is Peter Zierlien. I'm a videographer for
3 Golkow Technologies. Today's date is March 10th,
4 2016. The time is 9:54 a.m. This video deposition
5 is being held in Austin, Texas, in the matter of
6 Carol Jean Dimock versus Ethicon, Inc., for the
7 United states District Court, Southern District of
8 West Virginia at Charleston. The deponent is
9 Dr. Robert Shull.

10 Will counsel please identify yourselves for
11 the record?

12 MR. CANNON: Doug Cannon appearing on behalf
13 of the plaintiff.

14 MS. VAN STEENBURGH: Tracy Van Steenburgh on
15 behalf of the defendants.

16 THE VIDEOGRAPHER: Will you raise your right
17 hand, sir? Do you swear or affirm that the
18 testimony you give here today will be the truth,
19 the whole truth, and nothing but the truth?

20 THE WITNESS: I do.

21 ROBERT SHULL, called as a witness by the
22 Defendants, having been first duly sworn, testified as
23 follows:
24

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1 DIRECT EXAMINATION

2 BY MS. VAN STEENBURGH:

3 Q. Good morning, Dr. Shull.

4 A. Good morning.

5 Q. We met off the record, but I'll introduce
6 myself again. I'm Tracy Van Steenburgh and I represent
7 the defendants in a lawsuit brought by Carol Jean
8 Dimock, and we are here today to ask you some questions
9 about your expert opinion relative to Ms. Dimock's case.
10 You've had your deposition taken before, I take it?

11 A. Yes, I have.

12 Q. I will not go through all of the rigmarole in
13 terms of what we're going to be doing and the logistics
14 of it, then. The only thing that I do like to say is I
15 fancy myself as being somewhat articulate, but if I am
16 not and you don't understand a question that I've asked,
17 please ask me to rephrase it, ask it in a different
18 way; otherwise, I'll just assume you understood the
19 question when you answer it. Fair enough?

20 A. Yes.

21 (Exhibit No. 1 was marked for identification.)

22 Q. All right. Doctor, I'm showing you what's
23 been marked as Deposition Exhibit 1. I'll represent to
24 you that that is a notice of taking deposition in

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1 connection with the Dimock case along with a couple of
2 other cases you're going to sit for today, and as part
3 of the notice of taking deposition, you were asked to
4 some bring some materials with me -- with you. Did you
5 bring some today?

6 A. Yes, I did.

7 Q. Okay. And what did you bring with you as
8 materials?

9 A. I have a current copy of my curriculum vitae.

10 Q. Okay.

11 A. I have the notice that you have referred to
12 previously.

13 Q. Thank you.

14 A. I have the schedule of time I've spent in
15 preparation and the billing for the preparation. I
16 have the records, which are adjacent in a file box
17 which you can see at the end of the table. I have
18 the case-specific opinion from Dr. Shoemaker and the
19 medical evaluation when Dr. Shoemaker examined
20 Mrs. Dimock, and I have a chronology of records
21 relating to her care, which was provided to me by
22 Mr. Cannon's law firm to summarize the chronology of
23 events. I have a copy of the office visit Ms. Dimock
24 made when she saw me on the 25th of November, 2015.

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1 Q. With respect to the medical records that you
2 brought with you today, I noticed that some of them were
3 tabbed. Was there a rhyme or reason for the tabs that
4 you attached to the medical --

5 A. Only because the volume of records was so
6 great that it is impossible to get back to something
7 meaningful without having some type of a marker.

8 Q. With respect to the chronology that was
9 provided to you by Mr. Cannon's office, if you wouldn't
10 mind letting me take a look at that real quick.

11 A. (Witness complies.)

12 Q. Thank you. And it looks like this is a
13 chronology that has a date, the name of the provider,
14 the occurrence or treatment, and then a reference to
15 certain Bates numbers. This was prepared by counsel and
16 provided to you; is that right?

17 A. Yes.

18 Q. All right. And the -- some of the entries are
19 highlighted in yellow. Was that done before you got the
20 chronology?

21 A. You know, it's possible some of them were.
22 They are also notes of mine in when I was reading them,
23 so I highlighted some things and have some handwritten
24 notes in the margins.

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1 Q. And that's what I was going to ask, there was
2 some handwritten notes here, and I take it those are
3 your handwritten notes, correct?

4 A. Yes.

5 Q. All right. And then with respect to you had
6 mentioned that you had made some notes at or about the
7 time that you visited with and examined Ms. Dimock, and
8 that is contained in a transcribed set of progress
9 notes; is that right?

10 A. It is, and that has my own markings, because I
11 highlighted and excerpted from that for the final
12 report. I didn't include everything that I had dictated
13 and I wanted to highlight the areas I wanted to include.

14 Q. Okay. And just so I am clear, you examined
15 Ms. Dimock in Texas?

16 A. Yes.

17 Q. All right.

18 A. She came to my office in November of 2015.

19 Q. And your -- and you followed your normal
20 procedure, which was to conduct an examination and do a
21 dictation of your -- the history and the findings at or
22 about that same time?

23 A. On the same day.

24 Q. On the same day. Okay. And then those are

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1 transcribed by somebody else and put into a final
2 report?

3 A. Yes. They are dictated and another person
4 transcribes them and then I validate them.

5 Q. Okay. In addition to the chronology and your
6 notes, I also note there are some documents in the
7 notebook that look like there maybe is an operative
8 report, and that contains some of the notes that you --

9 A. Yes.

10 Q. -- had as well?

11 A. Yes.

12 Q. Is that right?

13 A. Yes.

14 Q. And that appears to be the operative report
15 from the date of implant by Dr. Housel; is that right?

16 A. I think there are several operative reports --

17 Q. Okay.

18 A. -- because she's had several procedures.

19 Q. All right. And you prepared an expert report
20 in connection with Ms. Dimock's case, correct?

21 A. Yes, I did.

22 Q. All right. And what is the date of that
23 report, if you don't mind, if you know?

24 A. It would be -- I don't know the exact date.

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1 It would be the last week of January of 2016, and it's
2 possible that I -- that Mr. Cannon's office has the
3 date which it was received. It was prior to February
4 the 1st, and it would have been one of those last few
5 days of January, 25th or 6th possibly. I don't remember
6 that for certain.

7 Q. And I don't know if this may help you, you
8 gave me a copy of your billing statement, and it looks
9 like you had prepared a draft and that you may have had
10 a final call with Mr. Cannon on or about the 26th of
11 January?

12 A. That's correct.

13 Q. So using that as the date, when were you first
14 asked to get involved in connection with the claims by
15 Ms. Dimock?

16 A. I believe the first correspondence I had with
17 Mr. Cannon's office was in the fall of 2015. I don't
18 remember the exact month. I don't have that letter with
19 me.

20 Q. Okay. And that was a direct contact from
21 Mr. Cannon's office to you, or is it through somebody
22 else?

23 A. It was through his paralegal originally.

24 Q. Okay.

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1 A. And then he and I corresponded. I emailed him
2 and/or called him to get information to decide if this
3 was something that fell into an area I had an interest
4 in and knowledge enough to be of assistance.

5 Q. And what kinds of -- I mean, did you ask him
6 for materials in order to review it to assess that?

7 A. No. I asked him mainly about the patient
8 herself, what the possible concerns are, and what were
9 his expectations. Did he simply want me to review the
10 record and contact him? Did he want me to write a
11 case-specific report, simply to see her in consultation?
12 I wasn't clear in the beginning what he was asking me to
13 do.

14 Q. Okay. And I noticed in some of the materials
15 that you brought with you there are some handwritten
16 notes. I'll strike that. It looks like these are from
17 something else.

18 What was it that Mr. Cannon asked you to do in
19 connection with the Dimock case?

20 A. Eventually, what he asked me to do, would I
21 see her for a medical evaluation, would I evaluate her
22 prior records, her current exam, and be willing to write
23 a case-specific report about her, I guess, fact sheet
24 would be the right word. I'm not sure I saw it at the

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1 time, what was contained in the fact sheet about her
2 injuries associated with the product that had been
3 implanted in her.

4 Q. And prior to that, you and Mr. Cannon had
5 talked about her case, and that was so that you could
6 assess whether this was something within your area of
7 expertise?

8 A. Yes. And to find out what he actually
9 expected someone to do, because I -- did it fit in a
10 calendar that I could do it? Was it something I was
11 knowledgeable about?

12 Q. And what was the nature of the scope of the
13 engagement, besides seeing her for evaluation,
14 evaluating her records; more specifically, were you
15 asked to provide some kind of opinion as to whether
16 there was a cause-and-effect relationship between the
17 implant and her injuries?

18 A. Yes.

19 Q. Okay. Now, were you asked as part of the
20 scope of your engagement to determine whether -- well,
21 let me strike that.

22 In your review, Ms. Dimock received a Prolift
23 device as part of her procedure that Dr. Housel
24 performed back in 2008, correct?

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1 A. That's accurate.

2 Q. And Dr. Housel also implanted something called
3 a TVTO vaginal sling, correct?

4 A. Yes.

5 Q. All right. Were you asked to provide an
6 opinion as to whether the Prolift device caused the
7 injuries that Ms. Dimock claims she now suffers?

8 A. I was.

9 Q. Okay. Were you asked to provide an opinion as
10 to whether the TVTO device caused any of the injuries
11 that Ms. Dimock claims she has suffered?

12 A. He asked if I was interested in that. I told
13 him I was not likely to be prepared to do that on the
14 TVT.

15 Q. All right. And why is that?

16 A. Because, one, we have a long record of
17 knowledge about TVT. We are reasonably familiar with
18 its success, with the side effects, and potential
19 complications. It's accepted as a method of treatment
20 for urinary incontinence. I, in fact -- I don't use a
21 TVTO. I do use a retropubic TVT, so I feel as if I'm
22 knowledgeable about that.

23 Prolift has a much shorter history with less
24 objective information about its indications,

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1 complications, and potential problems, and the truth is
2 that some of her physical findings could only be related
3 to the Prolift because of the areas in the vaginal canal
4 where the exposure is identified.

5 Q. So just so that we are clear, you are not here
6 today and have not prepared any report or are prepared
7 to give an opinion as to whether the TVTO in any way
8 caused any injury to Ms. Dimock; is that right?

9 A. That's accurate.

10 Q. Okay. Did you look at the records relative to
11 the implantation of the TVTO and her subsequent medical
12 treatment?

13 A. Yes, I did.

14 Q. Okay. And do you believe that the TVTO was
15 effective for her stress urinary incontinence?

16 A. To the best of my knowledge, it was helpful
17 for her stress urinary incontinence. She still had
18 urinary complaints. Probably not stress incontinence
19 but symptoms compatible with urgency incontinence or
20 overactive bladder.

21 Q. Okay. And urinary incontinence and overactive
22 bladder are usually not treated with a device such as a
23 TVTO; is that correct?

24 A. That wouldn't be a standard method of therapy

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1 for those complaints.

2 Q. Okay. And are you here today to provide any
3 opinions relative to any urinary incontinence issues
4 that Ms. Dimock might be currently experiencing?

5 A. Well, if you ask me questions about her
6 symptoms, if I can answer them appropriately, I will.

7 Q. Okay. And the question, I guess, more
8 specifically is have you been asked to provide any
9 opinions relative to whether Prolift has caused any of
10 the issues that Ms. Dimock currently experiences with
11 urinary incontinence?

12 A. Not with her current complaints. When I
13 looked at the records, there were some concerns possibly
14 related to urethral obstruction associated with the
15 Prolift and Dr. Norton's preoperative and intraoperative
16 notes indicate some of that, so I feel comfortable
17 answering questions about that if you ask about them.

18 Q. Okay. And with respect to Dr. Norton's
19 findings in her notes, there was never any finding of
20 any kind of urethral obstruction with Ms. Dimock; is
21 that right?

22 A. There was no objective evidence that she could
23 not empty her bladder effectively, for example.

24 Q. Okay. There are references in her record to

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1 some experience with urinary retention. Do you remember
2 seeing that?

3 A. Yes. What I don't remember, and maybe you
4 have that, but I don't remember seeing it, the
5 documentation of a continued what are called postvoid
6 residual volumes, elevated postvoid residual volumes.
7 There may be something. I don't recall that off the top
8 of my head.

9 Q. Okay. Well, the reason I ask is there are
10 some references in there to some of the medications that
11 she was taking that one of the side effects is urinary
12 retention. I don't recall if you saw that or not?

13 A. Yes.

14 Q. Okay.

15 A. She was taking some antispasmodics, and some
16 antispasmodics relax the bladder, and one of the
17 potential side effects is it may either take longer to
18 void or you may have incomplete voiding.

19 Q. Okay. Doctor, your report that you prepared
20 in connection with Ms. Dimock's case is based in part on
21 your review of her medical records, correct?

22 A. Yes.

23 Q. And is it also based in part on your medical
24 examination of Ms. Dimock?

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1 A. Yes.

2 Q. And then it's also based in part on your
3 clinical experience?

4 A. Yes.

5 Q. And also your review of the literature?

6 A. Yes.

7 Q. Okay. Did you review Ms. Dimock's medical
8 records prior to performing a medical examination of
9 Ms. Dimock?

10 A. I had access to some of her records that had
11 been given to me in advance, not the entire record, and
12 even if I had received all of those records, it would
13 have been impossible to review them before I saw her.
14 And then I spoke to her directly before examining her
15 about her own knowledge of the history of her
16 obstetrical history, surgical history, and her current
17 complaints.

18 Q. And I guess more specifically, when you said
19 you had received some records, do you recall, did you in
20 fact review some of her medical records prior to meeting
21 with her?

22 A. I cannot tell you for certain which ones, but
23 I believe that I had access to her operative note from
24 2008 and to at least some, if not all, of her explant

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1 procedures following that.

2 Q. Okay. And those would have been procedures
3 primarily performed by Dr. Norton?

4 A. Yes.

5 Q. Okay.

6 A. Normally, I would like to have those when
7 someone is being seen for evaluation after having had
8 prior surgery. It's helpful to see the operative notes
9 because in general they are more informative than the
10 history is.

11 Q. With respect to the medical records, how did
12 you decide which medical records to reference in your
13 report?

14 A. What I wanted to do was understand something
15 about her history before she had surgical management in
16 Utah. So there were some things in her record that I
17 could see, but that came in part from simply
18 interviewing her about her past surgical history when
19 she was living in California. And then in the remainder
20 of the records what happened now is when you, for
21 example, request a record or someone sends me a record,
22 it would be an exhaustive copying of every conceivable
23 thing, including in-hospital stays, a lot of nursing
24 documentation, which is appropriate for nurses to know

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1 about. It isn't necessarily something that would be
2 helpful in understanding the details of how the patient
3 feels or about the surgical procedure. So what I've
4 tried to do is find the parts of the record that
5 actually involve a face-to-face encounter with one of
6 the health-care providers, either in the outpatient
7 clinic or in the operating room or the recovery period,
8 as opposed to documentation for all of the other things.

9 Also with electronic medical records, many things
10 are repeated over and over and over again. I'm sure
11 you've seen that, so once you've read that particular
12 entry one time, it normally isn't necessary to read it
13 on every other time that it's repeated in the medical
14 record.

15 Q. Now, your report includes a summary of certain
16 medical records and also includes a -- your summary of
17 your examination of Ms. Dimock, correct?

18 A. That's accurate.

19 Q. All right. So let's talk a little bit about
20 the format. I'd like to talk about the examination and
21 when she came down to meet with you.

22 A. Yes.

23 Q. That was in November of 2015, correct?

24 A. November the 25th, 2015.

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1 Q. Okay. And where did the examination take
2 place?

3 A. In my office in Temple, Texas.

4 Q. Okay. And was anyone else present?

5 A. No, not with her. She came by herself, and I
6 inquired when she came if I were free to share her
7 information with Mr. Cannon, and she gave me permission
8 to do that. He wasn't there, but she was comfortable
9 letting me either copy him the records or -- I can't
10 remember if I spoke to him, quite honestly, but he had
11 access to the information in the record.

12 Q. Prior to the examination, did you talk with
13 any of Ms. Dimock's physicians?

14 A. No. And I haven't since.

15 Q. Okay.

16 A. I haven't spoken to anyone else about it.

17 Q. And the same question as to any of her family
18 members?

19 A. I haven't met anyone. I think she is single
20 and she has one child whom I've never met and never
21 spoken to.

22 Q. All right. How long did the examination take?

23 A. Her visit, I would say it was probably 45
24 minutes to an hour from the time I saw her, interviewed

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1 her, examined her, then she would get dressed and come
2 back to my office, and we sat down to discuss her
3 history, the physical exam, answer her questions, and I
4 tried to give her as much information as I had about
5 what I thought I saw and felt and what some options for
6 her would be regarding management of her pain complaints
7 primarily.

8 Q. And the recommendations or what you thought
9 about how to manage her pain complaints, are those
10 contained in your report?

11 A. Yes, they are. And they're --

12 Q. Was there anything else you shared with her
13 that is not in your report with respect to
14 recommendations on treatment?

15 A. No. And my expert report has a condensed
16 version of my entire outpatient recording, but the
17 entire outpatient encounter is in the records that I
18 have here.

19 Q. And just so that I am clear, the examination
20 you said was 45 minutes to an hour, and then after-
21 wards she came to your office and spent more time --

22 A. That was --

23 Q. -- or the whole --

24 A. -- the entire visit.

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1 Q. The entire visit --

2 A. Yes.

3 Q. -- was between 45 minutes and an hour?

4 A. Right.

5 Q. Okay. And with respect to the history that
6 you took from Ms. Dimock, did that occur at the
7 beginning, before the physical examination, or
8 afterwards?

9 A. It's before.

10 Q. Okay.

11 A. So normally, what I would do is introduce
12 myself to someone, particularly someone I've never met
13 previously, discuss the history in as much detail as
14 possible. Then after I've obtained the history, then
15 the patients prepare for -- I leave the room. The
16 patients prepare for an exam. I come back and examine
17 her. After the exam, she then gets dressed and after
18 she's dressed and comfortable, then she would come to
19 the office and we would discuss it.

20 Q. Very good. Thank you. And just so I'm clear
21 on logistics. During the time that you are taking the
22 history and doing the examination, are you
23 contemporaneously dictating?

24 A. No.

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Page 23

1 Q. Okay.

2 A. What happens now with electronic medical
3 records, you can enter all of those things while you're
4 interviewing the patient. I don't do that. I interview
5 them, discuss everything with them, and when they leave,
6 then I document the electronic records and dictate the
7 encounter.

8 Q. If -- do you have a copy of your report?

9 A. Yes. Of the expert report?

10 Q. Yes.

11 A. Yes, I do.

12 Q. There is a section in the ex report that
13 starts at Page 8 where it indicates you personally
14 interviewed and examined Ms. Dimock on November 25,
15 2015. If you would turn to that.

16 A. I see it.

17 Q. Okay. I want to make sure that I understand
18 the format. It looks as though you took the history and
19 have recorded the history that goes through Page 10 to
20 the bottom, where then you describe the examination; am
21 I correct on that?

22 A. It looks as if that's the case.

23 Q. Okay. Did you prepare this report yourself?

24 A. Yes.

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1 Q. And then on Page 11, there is a section that
2 starts in the middle of the page saying "Diagnosis"?

3 A. Yes.

4 Q. And that would be a diagnosis that you -- was
5 based on your taking the history and your examination
6 and evaluation; is that right?

7 A. Yes. That's still a continuation of her
8 personal visit with me on the 25th of November.

9 Q. Okay. And then on Page 12, starting at the
10 top, it looks to be the area where you start providing
11 information regarding your differential diagnosis and
12 your opinions relative to Ms. Dimock's injuries; is that
13 right?

14 A. Yes.

15 Q. All right. I'd like to ask you a few
16 questions relative to the history, so that I understand
17 what you were asking and what Ms. Dimock was telling
18 you, and this is kind of a question-and-answer kind of
19 format; is that right?

20 A. Sure.

21 Q. I mean, not here, but when you were talking to
22 Ms. Dimock?

23 A. Yes.

24 Q. Yes. All right.

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1 A. That's correct.

2 Q. And were you restricted in any way from asking
3 her any questions that --

4 A. Not to the best of my knowledge.

5 Q. Okay. So on Page 8, it refers to the fact
6 that she had a hysterectomy and an oophorectomy in the
7 mid-'90s. Do you recall whether that was a total
8 hysterectomy or a laparoscopic hysterectomy?

9 A. I don't know the answer to that.

10 Q. Okay. Would that make a difference to you in
11 terms of any of your opinions in the case?

12 A. No.

13 Q. Okay. Now, it also looks on Page 9 that she
14 said she'd never had any symptoms of fibromyalgia,
15 correct?

16 A. That's accurate.

17 Q. And was it that -- she reported she'd had no
18 history of chronic pain prior to having the mesh
19 surgery; is that right?

20 A. That's accurate.

21 Q. Okay. So how do you define chronic pain --

22 A. I would --

23 Q. -- as you have written it here?

24 A. In the history?

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1 Q. Right.

2 A. Well, I would ask a patient very specifically,
3 "Do you have a history of fibromyalgia, yes or no? Do
4 you have a history of migraine headaches, chronic joint
5 disease, rheumatoid arthritis, lupus, anything that
6 could be associated with chronic pain?"

7 Q. Okay.

8 A. And her response to that was she had no
9 history of any of those things prior to her surgery,
10 and, in fact, I'm not sure she even has a current
11 history of any of them, to be quite honest.

12 Q. Okay. In taking her history, did you talk
13 with her about any history of previous pelvic pain that
14 she had experienced?

15 A. In the past, I talked to her about
16 hysterectomy. It's not uncommon when a woman has a
17 hysterectomy that among whatever the reasons are, pelvic
18 pain may be one of the reasons, it may be associated
19 with menstruation, with ovulation, with poor support.
20 So it's reasonably common in a woman who has had a
21 hysterectomy that one of the complaints would have
22 been painful menstruation or painful ovulation.

23 Q. Did Ms. Dimock tell you that she had been
24 treated for pelvic pain syndrome in the past?

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1 A. I'm not aware that she had chronic treatment
2 for that. She may have had -- sometimes when she
3 developed abdominal or pelvic pain, it was seen
4 intermittently, but I'm not aware that was a chronic
5 issue with her.

6 Q. Okay. And just so you and I are on the same
7 page, when you say not a chronic issue, how would you
8 define that, that it's an ongoing -- well, you define it
9 for me?

10 A. Well, it'd be -- usually chronic means lasting
11 six months or longer, or is recurrent, maybe
12 intermittent over a period of years with the same signs
13 and symptoms.

14 Q. So to the best of her recollection in response
15 to your -- well, strike that.

16 Based upon the history that she provided to
17 you, you did not understand that she had had chronic
18 pelvic pain in the past, prior to the mesh surgery; is
19 that right?

20 A. That's correct.

21 Q. Okay. In the history, it looks like she told
22 you that prior to her surgery in 2008, she had engaged
23 in a relationship where she had had sex on a regular
24 basis, is that right, and never had -- sorry -- and not

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1 had complaints associated with sexual intercourse; is
2 that right?

3 A. Not -- that's accurate.

4 Q. Okay. And she told you that for about a year
5 prior to the surgery, which was in 2008, she had not had
6 any sexual intercourse; is that correct?

7 A. Yes.

8 Q. Is it your understanding based on talking with
9 her that from the mesh surgery to the time that you
10 examined her, she had not engaged in sexual intercourse?

11 A. That's correct.

12 Q. Now, in the history, it says approximately
13 three to six months before seeing Dr. Norton in 2010 she
14 developed complaints with what she calls pulling,
15 ripping, and a sense of stabbing pain in the pelvis.
16 There's a reference to her working with a bicycle pump?

17 A. I presume what she was doing is blowing up a
18 tire or bicycle tire or a ball or something that
19 required you -- if she had used one the way you or I
20 probably would, she would be moving up and down with her
21 hands to pump something.

22 Q. Okay. Did you talk with her any more
23 specifically than the fact that she had been working
24 with a bicycle pump at the time?

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1 A. No.

2 Q. All right. But was it your impression based
3 on what she told you that she recalls the onset of the
4 pain based upon that activity that she was engaged in in
5 using the bicycle pump; is that right?

6 A. She at least -- she mentioned that.

7 Q. Okay.

8 A. It's not uncommon sometimes for people to date
9 an important medical activity to something.

10 Q. Absolutely. And then she also told you it was
11 approximately three to six months before she saw
12 Dr. Norton in 2010 that she began to develop the
13 complaints of pulling and ripping and that stabbing
14 pain?

15 A. Yes.

16 Q. Okay. Did you see in the records that she
17 told Dr. Norton that it had been that way since the mesh
18 surgery itself?

19 MR. CANNON: I'll just object. I think it
20 mischaracterizes the record.

21 MS. VAN STEENBURGH: All right.

22 A. I think I would have to see that note.

23 Q. Okay.

24 A. I mean, I can't remember that right off the

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1 top of my head, but I'd be glad to look at the reference
2 if you would like me to do that.

3 Q. We'll -- I'll bring those out in a bit. On
4 Page 10, Doctor, it looks like you are indicating that
5 at your examination there were no signs of any vaginal
6 bleeding, correct?

7 A. That's accurate.

8 Q. And there was a reference to her having used
9 estrogen intermittently following her surgery in 2008.
10 Was that something that she reported to you or something
11 you gathered from the records?

12 A. Well, it's -- it became clear in the interview
13 I had with her that she had used estrogen part of the
14 time. She also later developed breast cancer, and I
15 think she stopped her estrogen temporarily at least
16 during the time she had the diagnosis in early
17 management of her breast cancer.

18 It isn't uncommon for me to see people who may
19 be on any number of medical regimens where their
20 persistence in taking something on a regular basis waxes
21 and wanes.

22 Q. And my question merely was the extent to which
23 you talked with her about what her estrogen history had
24 been. Do you have any more detail other than she had

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1 used it intermittently following the surgery?

2 A. Not in this note, I don't. There are
3 -- there's information in the various outpatient visits
4 she had with Dr. Sharp, with I think Dr. Summers was the
5 doctor treating her infections, so there are multiple
6 comments in Drs. Norton, Sharp, and Summers' note
7 regarding advice to use estrogen and whether she was
8 currently using it or not.

9 Q. Do you recall seeing in her records that from
10 the time of her hysterectomy until approximately the
11 time that she saw Dr. Norton, she was taking estrogen
12 via injection?

13 A. I don't have that documented.

14 Q. Does that refresh your recollection at all, my
15 asking that question?

16 A. No.

17 Q. Okay. Do you recall seeing anything in the
18 records that she was taken off of estrogen and -- by
19 Dr. Norton?

20 A. No.

21 Q. The injectable? Okay.

22 A. Oh, the injectable? No. She may have
23 transitioned to the topical estrogen. I don't remember
24 the exact comment about that, but that would be a

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1 logical thing to do in someone in whom you want to
2 treat specifically the vaginal tissue is ask them to
3 use topical estrogen.

4 Q. Do you recall seeing anything in Ms. Dimock's
5 records regarding any withdrawal she was having from no
6 longer taking estrogen via injection?

7 A. No.

8 Q. Okay. Now, in the next paragraph, she
9 indicates to you that she has no sense of any tissue
10 bulging outside the vagina, correct?

11 A. That's accurate.

12 Q. And when you report that she says that she
13 feels as if she is imploding on the inside of the
14 vaginal canal, can you be any more specific as to how
15 she was describing her feeling there --

16 A. Well --

17 Q. -- or is that -- are those just words that she
18 used and you wrote them down?

19 A. Those are her words, which I would take to
20 mean that's not a normal feeling and is not a pleasant
21 feeling, and then she subsequently described pain. So I
22 don't normally have patients use that particular word.
23 I didn't ask her to expand on it --

24 Q. All right.

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1 A. -- any more than she did.

2 Q. And when she said that she describes pain as
3 to her seat bones, do you know what she was referring to
4 when she said "her seat bones"?

5 A. Oh, I think she means when she was sitting
6 down, probably on what she wouldn't know would either be
7 her ischial tuberosities or the lower part of her sacrum
8 or coccyx, but in fact in that area there are also
9 muscles and other tissues which would be related to
10 sitting and hurting.

11 Q. The next paragraph describes a little bit
12 about her issues with incontinence, correct?

13 A. Yes.

14 Q. And this is what she reported to you, that
15 Dr. Norton had asked her to reduce her fluid intake
16 because there might be a connection between her urge
17 incontinence and the amount of fluid she was taking in?

18 A. Yes.

19 Q. All right. And, again, if you drop down a
20 couple of paragraphs, she describes the pain in her seat
21 bones and in the back part of the vagina, correct?

22 A. Yes.

23 Q. Was it your understanding that this is a
24 constant pain that she experiences?

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1 A. I believe she had told me. My later -- the
2 last sentence in that paragraph said that there has not
3 been a day or a week or a month where she's been
4 pain-free since her surgery in 2008. That would lead me
5 to think that she has pain on a regular basis, and it
6 varies in intensity on a scale of zero to 10 between a
7 four and a seven, and depending on what level it is, she
8 may use aspirin or ibuprofen. Sometimes she would use
9 Percocet, which has a synthetic codeine in it.

10 Q. So as far as you can tell, this is a constant
11 pain as opposed to an intermittent pain that she
12 experiences?

13 A. I think she has a constant level of pain and
14 intermittently it changes.

15 Q. Okay. In terms of the --

16 A. She has a baseline pain component with
17 intermittent changes in the intensity of the pain.

18 Q. All right. And her report is that she's had
19 that constant or baseline pain since the surgery in
20 2008; is that right?

21 A. Yes.

22 Q. All right. Now, with respect to the
23 examination that you performed, you note that external
24 genitalia, Bartholin, Skene's, and urethra area are

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1 remarkable in that she has puncture sites from her prior
2 trocar placement of the mesh products, correct?

3 A. Yes.

4 Q. Did you notice anything -- she had a procedure
5 involving the Bartholin gland. Were you aware of that?

6 A. Yes.

7 Q. All right. And is one of the puncture sites
8 related to that procedure, or are you saying that
9 they're all related to use of the pelvic mesh product?

10 A. It would be highly unlikely they would have
11 been related to Bartholin's gland, unless someone made
12 an incision in an unusual area.

13 In order to deploy the mesh arms, there's a
14 need to have puncture sites on the outside of the vulva,
15 in what's called the perianal area. Those puncture sites
16 sometimes heal where frankly it's quite difficult to see
17 where the puncture was, and sometimes it's easier to see
18 that. That could vary depending on wound healing or
19 individual characteristics of a patient. It could in
20 the case of early after surgery, it could be a
21 reflection of infection in the wound site.

22 The areas that I saw and commented on, I
23 didn't see any acute signs of infection, and I couldn't
24 expel anything from these puncture sites. They simply

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1 were there.

2 Q. Okay. And with respect to any of your
3 opinions regarding Ms. Dimock's injuries, are you going
4 to provide an opinion that her injuries were due in any
5 part to the use and placement of a trocar for insertion
6 of the device in this case?

7 A. Yes.

8 Q. And what's your opinion?

9 A. About the trocar use, you mean?

10 Q. Yes.

11 A. Trocars, in order to be used in the case of
12 a transvaginally placed mesh, have to traverse a number
13 of tissue planes, depending on whether the trocar goes
14 outside to inside or inside to outside, but the trocars
15 traverse the skin; the external skin; the underlying
16 fatty tissue, what's called fascia; muscles; the
17 connective tissue of the vagina; and the skin of the
18 vagina. So in one way or the other, the trocars
19 traverse all of those tissue layers and those tissue
20 layers contain vessels, nerves, and areas where
21 lymphatic drainage, for example, which you cannot see by
22 simply looking at the skin any more than you could look
23 at my hand and see everything underneath. It just
24 doesn't work that way.

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1 So the trocars are passed in an area where
2 presumably it's safe in terms of not injuring a major
3 artery, a major vein, or a major nerve, but when the
4 trocars are introduced, the mesh arms then are deployed.
5 In general, the trocars themselves have a smaller
6 diameter than the width of the synthetic product. So
7 the trocar creates a passageway and when the arms are
8 deployed, the arms are not going to look the same as
9 they do when they come out of the package, for example;
10 and depending on where the trocars traverse, it's
11 entirely possible that there are going to be small
12 nerves, small vessels, possibly larger nerves or vessels
13 that could be injured because the trocars are passed not
14 under direct visualization but by palpation. That's the
15 nature of using them for anything, so it's not possible
16 to see everything.

17 So in the case of the Prolift, which requires
18 multiple trocar passages, every time one is passed,
19 there is an opportunity for something to happen that you
20 wouldn't have anticipated, or every time an arm is
21 deployed, there is an opportunity for that arm of the
22 mesh product to lie adjacent to a nerve, a sensory
23 nerve, a muscle nerve. And then because of the
24 placement of these arms, the configuration invariably is

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1 going to be different than it is when the arm is simply
2 lying out and hasn't passed through any tissue. So the
3 trocars in this particular circumstance are important,
4 because she required multiple trocar passages in order
5 to deploy the arms in the mesh.

6 Q. Well, let me ask you a question, because I
7 heard a couple of things there. One, is it your opinion
8 that the trocar -- the trocar is used with respect to
9 the Prolift product itself, the trocars themselves
10 injured Ms. Dimock? Because I heard you say something
11 about the trocars, but also when the mesh arms were
12 deployed, that the placement of the arms could lie
13 adjacent to a nerve, so I wanted to make sure I
14 understood the difference between the two of those.

15 A. In the case of an immediate injury from the
16 trocar itself, what we would expect to see is the mesh
17 is deployed into the rectum, the bladder, or the
18 urethra. There is no evidence that the trocars actually
19 passed into the rectum or into the bladder or into the
20 urethra, so that would be one possibility, where the
21 trocar itself could have created an injury. There is
22 nothing to suggest that. The trocars could penetrate a
23 large blood vessel and there could be hemorrhage
24 associated with the trocar placement. There is nothing

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1 in the record to indicate that there was an immediate
2 hemorrhage.

3 The trocars could be placed so that instead of
4 the mesh being deployed under the vaginal skin, the mesh
5 could be deployed through the vaginal skin, and there is
6 no evidence in the record to suggest that happened. The
7 trocars do pass through innervated tissue with blood
8 vessels in it in order to create a path to bring the arm
9 back out. So in the sense that the trocars are
10 important, they create the pathway for the arms to be
11 deployed, and could they injure small nerves, small
12 vessels, impede the -- by direct trauma? The answer is
13 yes, they could.

14 So let's presume that there isn't any mesh
15 product, but you simply took a group of women and took a
16 trocar as big as basically a pencil and stuck it six
17 times into the vaginal canal and out through the outside
18 of the pelvis, could someone be injured from that, and
19 the answer is yes.

20 In her case, she didn't have the trocar go
21 through the bladder, urethra, or rectum. She didn't
22 have excessive bleeding, but she in fact could have had
23 trauma to those other structures, which could cause her
24 to have pain. In that case, would the pain be chronic

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1 or would it be self-limiting? In all likelihood in the
2 absence of actually severing a larger nerve, which could
3 happen, but there is no evidence that happened here,
4 trauma from the trocar passage itself is more likely to
5 have a self-limiting period where there is bruising,
6 swelling, and tenderness, but the trocar then brings the
7 mesh product into that same pathway, and the product is
8 there forever. So the issue, then, is could you get the
9 product there without the trocar, and you can't. That's
10 why they are trocar-based.

11 Q. So the question I had was -- I think the
12 answer is no, if I hear you -- that there was not any
13 immediate injury by virtue of using the trocar itself,
14 correct?

15 A. There is no evidence of that.

16 Q. No evidence of that. And that's a possibility,
17 but there is no evidence in this case, correct?

18 A. There is no evidence.

19 Q. All right.

20 A. We would see that if someone saw the trocar in
21 the bladder, felt it in the rectum --

22 Q. Right.

23 A. -- saw it in the urethra, saw it in the
24 vaginal tissue. I'm talking about through the vaginal

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1 skin. If we saw that, you could say, "Yes. The trocar
2 was in the wrong place and it did something it
3 shouldn't have done."

4 Q. And your opinion here is that the mesh itself
5 was the cause of the pain and other injuries that
6 Ms. Dimock suffered, not the trocars themselves,
7 correct?

8 A. The trocar in and of itself isn't. The
9 trocar -- the mesh couldn't have been deployed without
10 the trocar.

11 Q. Understood.

12 A. So however you separate that out.

13 Q. Okay. Is it possible during a native tissue
14 repair for there to be some kind of damage to any of the
15 nerves or tissue?

16 A. Yes, it is.

17 Q. Okay. With respect to your pelvic exam, I
18 note that the vaginal canal measures approximately seven
19 centimeters deep.

20 A. Yes.

21 Q. Is that within a normal range based upon your
22 experience?

23 A. It is. You know, everything is an average,
24 just sort of whether you're tall or short or heavy or

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1 thin. There is an average somewhere. Not everybody is
2 on the average. So seven centimeters for vaginal depth
3 would probably be on the lower end of normal as opposed
4 to a woman who has a vaginal depth that's 10 or 11
5 centimeters, for example; but it still would fall within
6 a range that's considered normal.

7 Q. And the reason I ask that is there are some
8 references in the record to different measurements for
9 Ms. Dimock's vaginal canal. Do you remember seeing
10 those in the record?

11 A. Yes, I did.

12 Q. And they range some place between three
13 centimeters and 10 centimeters, if I recall correctly?

14 A. Well, different parts are being measured.
15 There is a system for measurement of specific areas of
16 the pelvis. The acronym is POPQ, but the term is pelvic
17 organ prolapse quantification. That system was created
18 and published in 1966 -- 1996. I was on the committee
19 who helped to design this objective way to measure
20 things in the vaginal canal.

21 So we measure what's called the anterior
22 compartment, the posterior compartment, the depth of the
23 vagina, the vaginal opening, the perineal body. There
24 are a variety of things that can be measured and

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1 documented in a grid form. Several of her reports from
2 Dr. Norton have that grid; others simply indicate the
3 depth of the vaginal canal.

4 Q. And your measurement here was the depth of the
5 vaginal canal; is that right?

6 A. Yes.

7 Q. All right. Now, are you going to give an
8 opinion in this case that Ms. Dimock's vaginal canal was
9 foreshortened by virtue of the fact that she had the
10 Prolift device?

11 A. I don't think I said that anywhere.

12 Q. I don't think you did either. I just wanted
13 to make sure.

14 A. No.

15 Q. The answer is no?

16 A. No, I'm not going to do that.

17 Q. All right. When you did the pelvic
18 examination, you noticed that she had atrophy. What is
19 atrophy?

20 A. Atrophy in the vaginal canal is tissue that
21 has reduced or no estrogen stimulation.

22 Q. And what does that do to the tissue? Does it
23 make it thinner --

24 A. In general --

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1 Q. -- if there's no estrogen? I'm sorry.

2 A. In general, women who have atrophy of the
3 vaginal canal may have the tissue be thinner, less
4 lubricated, and if you were to be able to do a
5 microscopic examination, there is reduced blood supply
6 to the tissue in the vaginal canal.

7 Q. Okay.

8 A. The tissue then becomes less soft or
9 distensible.

10 Q. Less elastic?

11 A. That could be a term.

12 Q. Okay. Then you say she has greatly increased
13 pelvic floor muscle tone. What does that mean?

14 A. That means in general when a woman has a
15 pelvic exam, if you ask her, she can relax the muscles
16 that -- in the vaginal canal, what are called the
17 levator muscles. Many woman can relax that on request.
18 People who have chronic pain frequently cannot do that
19 because they anticipate something is going to hurt, and
20 human nature is to withdraw, and withdrawal usually
21 means contraction of the muscles.

22 Q. And you note that initially you could only do
23 a digital exam using your index finger, but it sounds
24 like later on she was able to relax her muscles, and

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1 you were able to do a two fingerbreadth exam?

2 A. I did. And then I took the speculum, which I
3 use. Instead of using the top and the bottom of the
4 speculum, I was able to use the bottom part only, so I
5 could retract the area between the rectum and the vagina
6 and look at the top part of the vaginal canal, the area
7 under the bladder. Then I could turn that around and
8 look at the area between the rectum and the vagina. So
9 she allowed me to do that, but it was only after those
10 muscles relaxed some.

11 Q. Okay.

12 A. That's not -- that would happen with people
13 that have pain. They have increased muscle tone.

14 Q. Well, and people who have a certain amount of
15 anxiety about examinations may tighten their muscles; is
16 that --

17 A. They may.

18 Q. -- true?

19 A. They may.

20 Q. All right.

21 A. And maybe because it hurts them. They may be
22 anxious because it hurts.

23 Q. Well, when she was able to relax the muscles,
24 you did an examination, and where did you find

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1 tenderness, if at all?

2 A. There were several things I found on exam.
3 One, on the anterior part of the vaginal canal, by the
4 urethra and bladder, I could feel a small area that had
5 a different consistency. My note indicates it was about
6 four centimeters inside the vaginal opening. There was
7 a well-defined area that could be scar tissue, could be
8 a foreign body. By touch, it was not necessary -- you
9 couldn't possibly tell for sure which one it is, but I
10 described it as about the size of a small bean, and she
11 was tender in that area.

12 Q. So when you palpated that, was it something
13 that moved under your touch, or was it a fixed feeling?

14 A. It had minimal movement.

15 Q. Okay.

16 A. And then she was more tender, actually, to
17 palpation on the opposite side of the vaginal canal near
18 the top of the vagina on her left side.

19 Q. Okay.

20 A. And on that side, I didn't feel this, whatever
21 that was, whether it was scarring or foreign body or
22 induration. I didn't feel that on the left side, but
23 she was tender.

24 Q. And as we sit here today, you don't know what

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1 the small, bean-sized object consists of, correct?

2 A. That's accurate.

3 Q. All right. Are you going to speculate as to
4 what you think it might be?

5 A. Well, I could tell you it's likely one of
6 several things. It could be scar tissue. It could be a
7 small piece of mesh that's there.

8 Q. Okay.

9 A. It could be something we didn't anticipate
10 that is not scar tissue or not a piece of a foreign
11 body, but that's not a likely thing to happen. There is
12 no way to know it until it's actually excised and
13 someone looks at it.

14 Q. I was going to say -- right. As you sit here
15 today, you don't know, correct?

16 A. That's accurate.

17 Q. All right. And then on the rectal exam you
18 say you noted some banding of tissue near the ischial
19 spines on both sides.

20 A. Yes.

21 Q. When you say "banding," what do you mean?

22 A. That means normally when someone has a pelvic
23 exam, including a rectal exam, there isn't any
24 definitive three-dimensional structure that feels the

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1 same as -- for example, I'll give you my hand as an
2 example, So -- and my finger, index finger and thumb
3 are like this. This tissue is very soft. If I do that,
4 that feels entirely different. That would -- to me,
5 that would feel like a band.

6 So in examining her on rectal examination,
7 what I felt near these landmarks, all the ischial
8 spines, are these areas that were tighter and more tense
9 and usually you don't feel that.

10 Q. Okay.

11 A. So that's not what you would find on most
12 people's exam. That could be scarring. That could be a
13 foreign body. It would be most likely one of those two
14 things.

15 Q. And your examination, you did not find any
16 erosion of the mesh, correct?

17 A. That's accurate.

18 MS. VAN STEENBURGH: All right. Can we go off
19 the record for a second?

20 THE VIDEOGRAPHER: Going of the record. The
21 time is 10:51.

22 (Recess was taken from 10:51 a.m. until 10:57 a.m.)

23 THE VIDEOGRAPHER: Back on the record. The
24 time is 10:57.

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1 BY MS. VAN STEENBURGH:

2 Q. Doctor, I'd like to make sure that we are on
3 the same page with respect to Ms. Dimock. What were the
4 procedures that Dr. Housel or Housel performed in 2008
5 relative to Ms. Dimock?

6 A. Ms. Dimock had previously had a hysterectomy.
7 When he saw her for evaluation, he identified cystocele,
8 rectocele, urinary incontinence. The procedures he did
9 basically were placement of the anterior and posterior
10 Prolift and placement of a transobturator tension-free
11 vaginal tape.

12 His note details several procedures, including
13 cystocele repair, rectocele repair, enterocele repair,
14 and sacrospinous ligament suspension, and paravaginal
15 repair. My interpretation of the note would be that he
16 identified the cystocele, rectocele, enterocele,
17 paravaginal defect, and the repair of those was
18 accomplished using the anterior and posterior Prolift.
19 In addition to that, he did the transobturator
20 tension-free tape and performed cystoscopy.

21 Q. So is it your interpretation of his operative
22 note that he did not do a sacrospinous ligament
23 suspension?

24 A. I do not -- let me just read that note one

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1 more time.

2 Q. Sure.

3 A. I do not see in the operative note that he
4 specifically exposed the sacrospinous ligament and
5 placed any sutures in that ligament to secure the
6 top of the vaginal canal or the graft, either one
7 really.

8 Q. And so the absence of a description in his
9 operative note is what leads you to believe he did not
10 perform the sacrospinous ligament suspension?

11 A. It would lead me to believe he didn't document
12 it if he did it.

13 Q. So it's possible he did perform it but did --
14 his documentation is less than perfect?

15 A. Well, I don't know that.

16 Q. Well, I don't know that either, but I'm --
17 we're trying to get to the bottom of what he really did
18 do here.

19 A. He didn't include a description of the
20 dissection to do a sacrospinous ligament fixation. Now,
21 whether he did it or not is a different issue.

22 Q. All right. And he refers to -- there's a
23 reference to a anterior and posterior colporrhaphy.
24 That was -- that can be done with a native tissue

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1 repair, correct?

2 A. Yes, it can.

3 Q. All right. And in this case, it's your
4 understanding in interpreting his operative note that he
5 used the Prolift device on the anterior and also on the
6 posterior, correct?

7 A. That's accurate.

8 Q. All right. And when there is reference in his
9 operative report to repair of the enterocele via vaginal
10 approach, what do you understand that to entail?

11 A. What he describes, an enterocele or the
12 enterocele was identified. An enterocele is a type of
13 hernia. It normally occurs between the tissue that
14 should support the top of the vaginal canal and the
15 rectum.

16 He says he identified an enterocele, and he
17 plicated that with zero Ethibond purse-string suture,
18 which would imply that he saw a hernia sac with the
19 peritoneal surface between him and the inside of the
20 abdominal cavity, and what he choose to do was take a
21 nonabsorbable suture and take a circular stitch around
22 this hernia sack. When he tied the suture, it should
23 have obliterated the sac. And the reason he used
24 purse-string, it would be very similar to the strings or

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1 cords on a coin purse, for example, where someone would
2 pull the ends of that and close the top of the purse.

3 So his enterocele repair was using that one suture to
4 reduce the size of the peritoneal sac that he saw.

5 Q. And based upon your experience, are you aware
6 as to whether Ethibond sutures ever erode to the
7 surface?

8 A. They may.

9 Q. Okay.

10 A. I use them quite regularly, actually, so I am
11 familiar with that. In general, what happens with an
12 Ethibond suture or anything similar that is not
13 absorbable, you would like it to be underneath any skin
14 incision, ideally with another layer of tissue between
15 the skin and it, so that the skin and the soft tissue
16 heal and the stitch is under it.

17 Sometimes what will happen is people will
18 still react to that and at some time in the future, that
19 stitch may be obvious on physical exam that it has been
20 exposed through the skin incision.

21 Q. And have you been able to eliminate the
22 possible exposure of the Ethibond suture in connection
23 with any of the procedures that Dr. Norton--strike that.

24 Have you been able to eliminate erosion of the

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1 Ethibond suture in the case of Ms. Dimock?

2 A. Well, it's a single stitch that he used.

3 There is no evidence in any of the descriptions that

4 someone saw a single suture and removed it. The

5 Ethibond usually will have some color to it. It could

6 be a -- it could be white. It could have a color to it,

7 but there is no description of a specific stitch being

8 removed, so I didn't consider that as the problem

9 because no one said they saw it, and it wouldn't have

10 been placed in the location where the different mesh

11 exposures were seen. So I think that's highly unlikely.

12 Q. But the best person to answer that question

13 would be Dr. Norton probably, yes?

14 A. Yes. Well, if you ask her personally. Her

15 notes don't reflect that, and she has thorough notes.

16 Q. Understood. Now, your opinions as I

17 understand them is that Ms. Dimock's acute and chronic

18 pelvic pain and acute and chronic vaginal pain are the

19 result of Prolift, correct?

20 A. Are you referring to a specific place in my

21 report now?

22 Q. Yeah. I'm looking at Page 12, and I want to

23 make sure I understand your opinion.

24 A. Okay.

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1 Q. So I'm actually going to repeat that so that I
2 split those two up. Are you offering an opinion in this
3 case that Ms. Dimock suffered an onset of acute pelvic
4 pain as a result of the Prolift?

5 A. Well, she -- in her history, which I obtained,
6 she had no pre-existing history of chronic pelvic pain,
7 fibromyalgia, or the other things we've reviewed. In my
8 history, she says that she began to develop pain
9 complaints following her surgery. Now, for something to
10 be acute, she may have had an acute onset of some pain
11 complaints, but acute implies that the pain or whatever
12 other symptom or sign it is, if it's acute, it would
13 occur, and then the implication is it would be resolved
14 some way or the other. So her issue really is chronic
15 pain.

16 Q. Okay.

17 A. Even though she may have had acute pain to
18 begin with, the issue is it evolved into a chronic
19 concern, which has interfered with her quality of life.

20 Q. All right. So just to make sure I understand.
21 Your opinion is that Ms. Dimock has experienced chronic
22 pelvic pain, which was caused by the anterior and
23 posterior Prolift; is that right?

24 A. Yes.

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1 Q. All right. And your opinion also is that she
2 has experienced and suffered from chronic vaginal pain
3 caused by the anterior and posterior Prolift?

4 A. Well, when you say pelvic pain --

5 Q. Well, you have pelvic and vaginal here.

6 A. I understand.

7 Q. Okay.

8 A. Pelvic pain can be a variety of things. It
9 can be muscle pain, for example, in the vaginal canal --
10 or in the -- not in the -- muscles not in the vagina.
11 It could be muscles in the pelvis, vaginal -- or it
12 could be chronic bladder pain, for example, and there's
13 a typical history for chronic bladder pain.

14 It could be chronic bowel complaints. There's
15 a history for chronic -- I don't mean she has the
16 history. There are histories for chronic bladder pain.
17 There are histories for chronic bowel pain, which are
18 different than her complaints.

19 Then vaginal pain, most women would describe
20 vaginal pain as a sensation that they may have either
21 with having something placed in the vaginal canal, like
22 a speculum or a tampon or a sex toy, or to have sexual
23 intercourse, so vaginal pain usually implies something
24 inside the vaginal canal, and pelvic pain is more likely

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1 to be considered in the nerves, the connective tissue,
2 the muscles of the pelvis. And even though she may
3 describe her complaints as shooting pain in the vagina,
4 I don't doubt that she has them, so that could be
5 classified as vaginal pain or pelvic pain, either one.

6 Q. All right. So I just want to make sure that I
7 was understanding what your opinions are. So one
8 opinion that you are going to offer in this case is that
9 she, Ms. Dimock, suffers from chronic pelvic pain caused
10 by the anterior and posterior Prolift, correct?

11 A. Yes.

12 Q. All right. Are you also going to offer an
13 opinion that she suffers from chronic vaginal pain
14 caused by the anterior and posterior Prolift based on
15 your definition of vaginal pain?

16 A. Yes.

17 Q. All right. You are also going to offer an
18 opinion that she experienced repeated episodes of mesh
19 exposure that were caused by the anterior and posterior
20 Prolift, correct?

21 A. Yes.

22 Q. All right. So let me ask you a couple of
23 questions and let's start with erosion. Ms. Dimock
24 underwent surgical procedures to remove eroded mesh on

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1 more than one occasion, correct?

2 A. That's correct.

3 Q. And if my notes are correct, she underwent
4 that in four instances?

5 A. Yes.

6 Q. And as far as you know, there have been no
7 other instances where she has undergone any kind of
8 excision or surgical procedure for erosion of the mesh
9 since 2014, correct?

10 A. She did not describe it to me, and I didn't
11 see anything in her records to indicate that.

12 Q. All right. In some of the procedures where
13 she underwent excision of the mesh, also involved lysing
14 adhesions or releasing the mesh arms, correct?

15 A. That's accurate.

16 Q. All right. Now, with respect to erosion, is
17 it your opinion that every erosion of mesh constitutes a
18 serious complication?

19 A. In our literature there is an ongoing
20 discussion about the proper term to use to describe,
21 Is it mesh exposure? Is it something eroded or not? So
22 in the case of mesh exposure, what may happen, as I
23 understand it, is the patient herself may see or feel
24 the mesh outside the vaginal incision in the canal, or

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1 the doctor may see it, and then they respond to topical
2 estrogen treatment. They may respond to observation.
3 It may respond to excising a small amount of mesh in the
4 examination room in the office, for example.

5 Erosion, in my mind, usually means something
6 that occurs at a later time away from the index surgery,
7 frequently involves bleeding, spotting, discharge, could
8 involve pain for the sexual partner, for example, and it
9 could involve pain for the patient.

10 Erosions possibly could respond to topical
11 estrogen. Depending on the surface area of the erosion
12 and a variety of other things, that may be a reasonable
13 thing to offer a patient. And then if they respond well
14 to that, that may be the end of it, but in the case
15 where that doesn't, the patient doesn't respond, then
16 excision of the mesh is the only other therapeutic
17 option.

18 Some doctors advocate removing only the part
19 of the mesh that's visible and closing the skin edges
20 over it. There are a few surgeons who recommend
21 attempting to remove all of the mesh, which has been
22 implanted. Most surgeons feel that trying to remove all
23 of the mesh, particularly when mesh arms have been
24 deployed, has a potential to create its own set of

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1 complications.

2 Q. And, Doctor, I appreciate that. I think we're
3 getting a little off topic, and I only have a limited
4 amount of time, so the question was whether you consider
5 the mesh exposure here for Ms. Dimock as you've
6 described in your report as a serious complication?

7 A. Well, it's serious enough that when we report
8 on complications following surgery, a complication
9 requires -- something with an operative intervention is
10 a high-level complication.

11 There are scales for complications, the Dindo
12 scale, for example. So some things require observation,
13 some require medicine, some require something, but
14 surgery, surgery moves up the scale of the significance
15 of a complication.

16 Q. Right.

17 A. Because it requires an anesthetic, a recovery,
18 and the whole works.

19 Q. All right. So in your mind, a serious
20 complication involving exposure would be one that
21 requires surgical intervention, as opposed to topical
22 treatment with estrogen, for example, correct?

23 A. That's accurate.

24 Q. Or what about someone who the mesh exposure is

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1 trimmed in an in-office procedure, would that be a
2 serious complication?

3 A. That would fall on the lower level of
4 significance.

5 Q. Okay. Now, with respect to your opinion here,
6 how is it -- in summary form, without going into long
7 detail, you say the Prolift itself caused the exposure.
8 Can you tell me what the basis of that opinion is?

9 A. Yes.

10 Q. And what is that?

11 A. She has a foreign body implanted in the vagina
12 that has a significant surface area. The product itself
13 and the package has a significant surface area.

14 In the case of Mrs. Dimock, she had an inter-
15 val after her surgery that could have been 18 months or
16 20 months where the mesh was not exposed, and then her
17 complaints with pain increased. She had evidence of
18 the exposure, and what I think most likely happened is
19 the mesh product itself became shorter, either through
20 scar contracture or contracture of the mesh product,
21 and as it became shorter, there are fixed arms of
22 the mesh that have gone through the muscles, nerves,
23 and tissue in the vaginal canal, and those arms rarely
24 move in terms of becoming looser. So the arms became

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1 tighter in much the way this becomes tight, and when the
2 arms became tight, the central portion also became
3 taught, interfered with blood supply to the skin, erodes
4 through the skin, and then the skin is not able to heal
5 over that. And the treatment and surgery for skin
6 drainage, skin erosion, infection, and there is a
7 foreign body, the treatment is to remove the foreign
8 body, and in this case, the Prolift is the foreign body.

9 Q. Right. And we're talking about erosion, so as
10 I understand your -- the basis for your opinion is that
11 the Prolift product, either through scar tissue or
12 because of the product itself, becomes more taught,
13 closer to the surface, and then eventually the mesh then
14 goes through the skin surface and is exposed; is that
15 what I heard you say?

16 A. Yes, you did.

17 Q. All right. So did you take into consideration
18 at all the -- this patient's characteristics in your
19 opinion that it was the Prolift that caused the erosion?

20 A. Do you have a specific question about the
21 patient characteristics?

22 Q. Sure. She's a smoker, right?

23 A. Yes.

24 Q. And she's been a smoker for 40 years, correct?

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1 A. Yes.

2 Q. What does smoking do to tissue?

3 A. Smoking affects estrogen metabolism. So the
4 way smoking affects tissue in the vaginal canal is when
5 women, primarily, make estrogen and it's metabolized in
6 the body and they don't smoke, the estrogen metabolize
7 to something that may have a significant amount of
8 biological activity.

9 Smoking changes the metabolic pathway so that
10 the estrogen metabolism pathway then results in an
11 estrogen that is less biologically active. So if you
12 see someone, for example, a woman, particularly who is a
13 chronic smoker, frequently her skin will show that, the
14 skin in her face. But the skin in the vaginal canal
15 will more likely have reduced blood supply and be thin
16 and dry.

17 Q. And so could her vaginal tissue be a
18 contributing factor to the mesh erosion in her case?

19 A. It's possible.

20 Q. All right. How about the fact that Ms. Dimock
21 engaged in self-examinations of her vaginal canal? Did
22 you see that in the medical records?

23 A. I did.

24 Q. Could self-examination have contributed to any

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1 mesh erosion?

2 A. I think that would be extremely unlikely. It
3 would be less likely, for example, in a woman who is
4 having intravaginal intercourse or a woman who wears a
5 tampon or a woman who has a speculum exam, so I think
6 that would be a highly unlikely scenario unless you're
7 dealing with someone who does self-mutilation. There is
8 no evidence she does that.

9 Q. The erosion is a potential adverse consequence
10 of using mesh, is it not?

11 A. Yes, it is.

12 Q. And that's something that Ethicon warned about
13 it its IFU?

14 A. In the most general terms, not in very
15 specific terms.

16 Q. Well, it did identify that as a potential
17 consequence that might result in further surgical
18 procedures, did it not?

19 MR. CANNON: I'll just object; argumentative.

20 A. Without quantifying when and how many times.

21 Q. And did you read Dr. Housel's deposition?

22 A. I did.

23 Q. And he was aware that erosion was a potential
24 consequence, correct?

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1 A. I think everyone knows superficially that it's
2 possible. What people -- including, I would say, the
3 majority of doctors and probably all patients. They
4 don't understand that that event could occur at any time
5 in the future and may or may not require multiple
6 interventions to resolve.

7 Q. And when you say that, have you done a study
8 that forms the basis of that opinion?

9 A. No. I've read literature that would form the
10 basis.

11 Q. Okay. And what literature are you relying on
12 for that?

13 A. The literature -- well, part of it comes from
14 the University of Utah, for example, in evaluating women
15 who were referred for mesh exposure and mesh
16 complications, and on average, women required at least
17 two and frequently more procedures to resolve the
18 current issue. And the potential concern about that is
19 you don't know in the future how many of those people
20 are going to come back again, so that's a snapshot in
21 time.

22 There's a report from the Cleveland Clinic,
23 Mayo Clinic, University of Michigan, so there are
24 multiple reports on the requirement for requiring more

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1 than one intervention to resolve these issues.

2 Q. And intervention, are you referring to
3 specifically a surgical intervention --

4 A. Yes.

5 Q. -- as opposed to an in-office procedure or
6 topical treatment?

7 A. It could be any or all of those, but
8 specifically surgery.

9 Q. All right.

10 A. But it could include other things also.

11 Q. Doctor, with respect to your opinion regarding
12 the chronic pelvic pain that you -- that Ms. Dimock
13 claims to experience, your opinion is that the chronic
14 pelvic pain was caused by the Prolift, correct?

15 A. Yes.

16 Q. All right. And what is the cause of that
17 pain? What is the mechanism as you understand it?

18 A. Okay. In her particular circumstance, what I
19 believe transpired with her, she had the product placed.
20 I've already indicated to you the trocar passage in and
21 of itself is a traumatic event. Surgery is traumatic.
22 So trocar passage is traumatic, and she may have had
23 some of her earlier complaints related to multiple
24 trocar passages with an expectation that's reasonable

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1 that that's going to improve.

2 The fact is she acquired a set of complaints
3 which haven't improved, despite several different
4 attempts at therapy. And I believe the pathophysiology
5 of what's happened is the mesh was put in place, may
6 have been placed with relatively little tension, for
7 example, and may not have bothered her for 18 months,
8 particularly. I mean, it may have had some low level
9 concern, but didn't come to her attention.

10 But as time goes on, the mesh contracts.
11 There's degradation of the mesh. There's a chronic
12 inflammatory response. There are nerves that grow into
13 the mesh product. Those nerves can be sensory nerves,
14 carrying pain, and they -- the product goes through
15 muscle. It goes through the skin of the -- through the
16 skin outside the pelvis and it goes underneath the
17 vaginal skin, so there are any number of places where
18 nerves could be entrapped and chronically irritated.

19 Q. Well, let me ask you this: Doctor, is the
20 cause of the pain, you know, as you say nerves are
21 entrapped, you said the mesh contracts, is it the mesh
22 that contracts, or is it the tissue around the mesh that
23 contracts?

24 A. Well, there is evidence to show the mesh

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1 itself contracts. There is literature to demonstrate
2 that, but it could be a combination of scar tissue and
3 mesh. But the fact is it's highly unlikely to see
4 someone who doesn't have mesh products put in place to
5 have these ongoing chronic pain problems that require
6 multiple surgical interventions. That's a --

7 Q. Well, let me ask you this. You attribute all
8 of her chronic pelvic pain issues to the Prolift
9 product, correct?

10 A. I think that's likely, yes.

11 Q. Okay. Did you -- when you were considering
12 whether it was due to the Prolift product, did you take
13 into consideration other procedures she had had?

14 A. Such as?

15 Q. The hysterectomy.

16 A. I did, but there is no reason to think that
17 would be related to her current complaints.

18 Q. Well, I mean, you said any surgery is
19 traumatic, and there could be a development of scar
20 tissue relative to a hysterectomy; is that true?

21 A. Not the complaints she has.

22 Q. Okay. How about the -- you're aware that she
23 had a wedge resection in 1972, correct?

24 A. Of her ovaries?

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1 Q. Yes.

2 A. Yes.

3 Q. And, in fact, those procedures were
4 discontinued because of the high rate of adhesions
5 that occurred afterwards; is that right?

6 A. Related to fertility, not pain.

7 Q. Well, as a matter of fact, Ms. Dimock here,
8 did she not make complaints about ovarian pain in her
9 pelvis as part of the procedure when she was seeing
10 Dr. Norton?

11 A. She may have said it seems similar to ovarian
12 pain.

13 Q. And so can you eliminate the fact that there
14 may have been some adhesional -- adhesions relative to
15 the wedge resection, and that was causing some of the
16 pelvic pain?

17 A. Well, the only way to be certain that someone
18 has adhesions in the abdomen at all, whether they have
19 pain or not, the only way to be certain of that is to
20 look surgically, and no one looked in her abdomen
21 surgically to see.

22 Q. Right. And I'm just trying -- I mean, you
23 have come to the conclusion that all of her chronic
24 pelvic pain is due to the fact that she had the Prolift

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1 device and I wanted to understand whether you considered
2 other alternatives?

3 A. Oh, yes, I did. But let's just use that
4 specific example. So 40 years ago she had wedge
5 resection of her ovaries and didn't have the current
6 complaints she has now. In 2008, she had the Prolift
7 implanted and she's acquired these complaints. So just
8 thinking about it logically, why would she have had a
9 surgery 40 years ago that didn't bother her until she
10 had the Prolift put in?

11 Q. And so she had an additional surgical
12 procedure that could, in fact, have affected the
13 adhesions from the wedge resection possibly? Yes?

14 A. That would be highly unlikely because the
15 surgery that she had done in 2008 did not involve
16 entering the abdominal cavity.

17 In Dr. Housel's note where you asked me about
18 the enterocele, he specifically didn't enter the
19 abdominal cavity, so if she had adhesions following the
20 wedge resection, which it's possible she had them,
21 they're inside the abdomen. That would be similar in
22 this case to the four of us who are in this room and
23 there is somebody out there. So could she have
24 adhesions out there, but we're talking about everybody

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1 in here? That's conceivable, but that's not a logical
2 conclusion to draw.

3 Q. Are you making a distinction between the
4 pelvis and the abdomen in terms of your --

5 A. In terms of --

6 Q. You said the adhesions relative to the wedge
7 resection would appear in her abdomen --

8 A. Yes.

9 Q. -- as opposed to her pelvis?

10 A. That's correct.

11 Q. Okay.

12 A. Through the abdominal cavity.

13 Q. All right.

14 A. No. That is correct. It would be what is
15 called "intraperitoneal."

16 Q. All right.

17 A. Now, does the peritoneal cavity go down into
18 the pelvis? It does, but those adhesions would be in-
19 side the peritoneal cavity, and none of the procedures
20 she had done entered the peritoneal cavity, so it would
21 be -- I guess anything is possible -- that would be so
22 unlikely that there'd be something inside her abdomen
23 which is exaggerated by what was done here, unless a
24 trocar was passed inadvertently into her abdomen and

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1 injured her bowel. Could that happen? It could, and
2 if that were to happen, the patient would be sick.

3 Q. All right. You didn't see evidence of that
4 here?

5 A. No. She didn't --

6 Q. Let me --

7 A. She didn't report any of it. She would have
8 been sick, sick, sick if that happened.

9 Q. Let me ask you this just very briefly.

10 A. Uh-huh.

11 Q. She underwent a wedge resection, correct?

12 A. That's -- yes.

13 Q. And a hysterectomy, correct?

14 A. Yes.

15 Q. And an appendectomy, correct?

16 A. Yes.

17 Q. And she's also complained of pelvic plain
18 issues related to GI issues, correct?

19 A. Right.

20 Q. And she's been diagnosed with diverticulitis?

21 A. In 2013.

22 Q. Okay.

23 A. Not in 2008 or '09 or '10.

24 Q. Well, and she's previously had abdominal pain

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1 for which she has undergone examination and treatment in
2 the past, prior to 2008, correct?

3 A. She has, that's accurate.

4 Q. Yes. A left lower quadrant pain, some right
5 lower quadrant pain; is that right?

6 A. That's accurate.

7 Q. All right. And Dr. Housel's procedure, was
8 there any potential by virtue of the fact that he
9 engaged in surgery that there may have been a potential
10 for scarring?

11 A. From the pelvic reconstructive surgery, you
12 mean, in the vaginal canal?

13 Q. Other than the Prolift, he also performed --
14 it's a little questionable in your mind as to whether he
15 performed the ligament suspension, correct?

16 A. Yes.

17 Q. All right.

18 A. And in general, if someone does sacrospinous
19 ligament suspension, in general, that is done on either
20 the left or the right side. Since his note doesn't
21 describe what he did anyway, we don't know if he did
22 left side, right side, or both sides, so --

23 Q. But can you eliminate that procedure as a
24 possible source of any pelvic pain she might have?

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1 A. Well, the natural history of pain following
2 sacrospinous ligament suspension is when that operation
3 is performed in America, it normally is performed on the
4 patient's right side usually. It could be the left, but
5 usually the right, and of the women who have
6 sacrospinous ligament suspension, what may happen is in
7 the early recovery and for the first eight or 10 weeks
8 after surgery, maybe one out of 10 or one out of eight
9 patients may say they hurt some on the side of the
10 suspension.

11 The natural history is that pain goes away.
12 So there aren't any syndromes described that I'm
13 familiar with that says a person who has sacrospinous
14 ligament suspension and then 18 months, 24 months, some
15 time in the future, they acquire these unremitting pain
16 complaints.

17 Q. Can you eliminate that, then, as a source of
18 her pain complaints?

19 A. I wouldn't have considered it as the source of
20 chronic pain complaints, and I don't think anyone who is
21 knowledgeable about the procedure would.

22 Q. How about the plication procedure that he
23 engaged in with respect to the enterocele?

24 A. I think that --

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1 Q. Can you eliminate that as a possible source of
2 pelvic pain?

3 A. That is so highly unlikely it would like being
4 hit by lightning.

5 Q. Can you eliminate it as a possibility?

6 A. I would.

7 Q. Okay. Can you eliminate any patient
8 characteristics involving Ms. Dimock as a factor in her
9 chronic pain?

10 MR. CANNON: I'll just object; ambiguous.

11 A. Specifically?

12 Q. Sure. Dr. Norton refers to Ms. Dimock's
13 patient characteristics specifically about the fact that
14 she has unusual scarring. Do you remember seeing that?

15 A. Uh-huh.

16 Q. And do you agree with Dr. Norton's statement
17 in the medical records that some patients are not as
18 suited as others for use of the Prolift device?

19 A. I think that's probably true. It may be no
20 one is suited for it. How's that?

21 Q. Well, she also said that some people have
22 successfully undergone surgery using the device and
23 others have not. Do you agree with that?

24 A. I --

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1 MR. CANNON: Well, I just -- if we've
2 got the record, I think that's the best thing to
3 look at.

4 MS. VAN STEENBURGH: Sure.

5 A. Do I agree that some people have had the
6 procedure and they haven't presented with complaints? I
7 feel sure that's the case.

8 Q. Okay.

9 A. Now, what I don't know is what's going to
10 happen to those women in the future, and no one knows
11 the answer to that.

12 Q. Well, that's true with surgery as well with
13 using native tissue, is it not?

14 A. It's much less likely true, because we have
15 a hundred-year history of native tissue, 150 since
16 anesthesia, and we have a -- in this particular case, we
17 have a 10-year history, so they aren't the same.

18 Q. Doctor, would you agree with me that Ethicon
19 warned about adhesion formation and contracture in its
20 IFU?

21 A. I understand from reading the IFU that in very
22 general terms there was a laundry list of things that
23 were listed.

24 Q. The question was --

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1 A. Yes.

2 Q. Yes. Okay. Thank you. So let me make sure
3 that I understand the basis for your opinion with
4 respect to her pelvic pain. Doctor, it's your opinion
5 that her chronic pelvic pain, which she claims to
6 currently experience, is the result of a combination of
7 the contraction of the mesh and contraction of scar
8 tissue; is that right?

9 A. I'm sure they're associated with one other.

10 Q. Okay.

11 A. That the mesh incites inflammation, incites
12 scar tissue, the mesh contracts, the wound contracts,
13 nerves are irritated, the vascular supply is modified.
14 They're all -- yes, they all go together.

15 Q. Okay.

16 A. Incited by having a foreign body in the
17 pelvis.

18 Q. Well, as a matter of fact, any time you put a
19 foreign body into a human, there is some kind of foreign
20 body reaction, is there not?

21 A. There could be. This one happens to be one
22 with a great surface area and then placed in a
23 contaminated part of your body, which flies in the face
24 of all surgical principles.

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1 Q. Doctor, in your -- and you may be asked this
2 in a more general way, are you relying on some
3 particular literature that -- for the opinion that
4 there's a greater chance of inflammation and chronic
5 inflammation by virtue of the fact that this is placed
6 in the contaminated area of the body?

7 A. Yes.

8 Q. Okay. And what's that literature?

9 A. Well, it's all -- it's the history of medicine
10 and surgery that placing a foreign body in a
11 contaminated field is poor surgical judgment.

12 Now, do we do that sometimes? When we operate
13 through the vaginal canal, yes, because the vaginal
14 canal is never sterile. So when we operate through the
15 vaginal canal and we use whatever procedures we use,
16 suture material, let's say, we're putting it into a
17 contaminated field. What happens, then, part of the
18 time and in many cases, the suture material dissolves,
19 so in a period of, let's say, 90 days or less, for all
20 practical purposes, that suture material has been
21 metabolized and is gone.

22 Sometimes -- and I do this -- I may use
23 nonabsorbable sutures, pieces of suture, to accomplish
24 part of the surgery, and occasionally some of those

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1 sutures will be exposed in the vaginal canal, and I can
2 see them and I can remove them in the office or I may
3 treat someone to estrogen hormone.

4 The thing that is different here is there is a
5 significant surface area of material that is not only
6 placed in the vaginal canal, but by virtue of using the
7 trocars, that same material is brought out through
8 multiple tissue layers in the bony and muscular pelvis.
9 So the product, then, is exposed to all of this
10 contamination in the vagina, in the muscles of the
11 pelvis, it just is. That's what happens.

12 Q. Well, Doctor, is there a difference between
13 infection and inflammation?

14 A. Inflammation --

15 Q. Is there a difference?

16 A. Yeah, there could be, yes.

17 Q. Okay. And are you talking with contamination
18 and bacteria, are you talking about infection or
19 inflammation?

20 A. Well, I'm talking about both actually
21 because --

22 Q. Do we have any evidence here that Ms. Dimock
23 suffered from a chronic infection as a result of having
24 the Prolift?

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1 A. Well, you -- in the path reports are the
2 foreign-body giant cells, so you see chronic
3 inflammation which leads to pain, for example.

4 Q. Let me ask you the question, though. Is there
5 any evidence of any kind of chronic infection with
6 Ms. Dimock that you've been able to identify?

7 A. Well, let me look at the path reports. I'm
8 going to see exactly what they said. I'll read what the
9 pathologist said. Did she have -- to answer your
10 question: Did she have an abscess in the pelvis? Did
11 she require hospitalization for treatment of high
12 temperature elevated white blood count? No, she didn't.

13 Q. So you indicate that the path reports show --

14 A. No. I'm going to read the path report here.

15 Q. I'm sorry.

16 A. If I find it.

17 Q. I thought you were answering my question about
18 infection.

19 A. Well, I am. I just wanted to find the path
20 report and see what the pathologist said.

21 Q. Okay.

22 A. Okay. This is from February 2010. The
23 pathologist says, "Foreign material with adherent
24 benign squamous mucosa exhibiting chronic inflammation

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1 and foreign-body giant cell reaction."

2 Q. That doesn't mean infection, correct?

3 A. It means inflammation.

4 Q. Right. And inflammation, with any foreign
5 body, you would expect some of that reaction, would you
6 not?

7 A. Yes.

8 Q. Okay.

9 A. And that would be why you would take the
10 foreign body out. So if you stuck a splinter in your
11 finger, you wouldn't leave it there.

12 Q. So if I had a heart valve and there is
13 inflammation around the heart valve, you'd take it out?

14 A. That's different. But the answer may be yes,
15 but the difference is the heart valve is placed in a
16 noncontaminated area of the body. These meshes are
17 placed in a contaminated part of the body.

18 Q. And contamination, in your definition, that's
19 bacterial contamination, correct?

20 A. In the vaginal canal, yes.

21 Q. All right. That's all.

22 A. The path report from October 2010, chronic
23 inflammation.

24 Q. Again, no sign of infection, correct?

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1 A. Not on those two. I will see if I can find
2 the rest of them. The path report from 2014, the
3 pathologist did not see mesh on that one. I think we
4 knew that -- you knew that already.

5 Q. Right.

6 A. And then there is one other path report that I
7 don't have in front of me so -- but I have those three,
8 two showed chronic inflammation and one showed just scar
9 tissue.

10 Q. And none of them showed any kind of infection,
11 correct?

12 A. Not acute infection.

13 Q. All right. Doctor, do you remember seeing a
14 reference in the medical records to the fact that
15 Ms. Dimock was noticing -- let me see if I can get it
16 correct -- staples in her pelvis?

17 A. She may have described that.

18 Q. And Dr. Norton talked to her about that,
19 correct?

20 A. Uh-huh. But there weren't any staples in her
21 pelvis, not in her vagina. People use different terms
22 to describe things, so patients by and large --

23 Q. That's okay. You don't have to go on. I was
24 just asking the question. There is a reference in the

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1 records to a permanent suture from the Bartholin gland
2 repair, though, correct?

3 A. Right.

4 Q. All right. Doctor, are you claiming that pain
5 Ms. Dimock expresses relative to her levator ani muscles
6 is related to the Prolift device?

7 A. Yes.

8 Q. And how is it related?

9 A. Well, chronic inflammation, irritation incites
10 a reaction in the tissues, and those trocars go through
11 muscle. That's what they do. They go through levator
12 muscles. That's what they're designed to do, and then
13 they deploy mesh in there, and then the muscles heal the
14 tract. The mesh gets smaller. It gets inflamed. The
15 muscles contract. There are nerve fibers.

16 This isn't a giant leap to presume that if I
17 stuck something as big as a pencil in you six times and
18 put a product and pull it out six times that it's going
19 to hurt somewhere.

20 Q. And so it's your opinion that any pain that
21 she has experienced in her levator ani muscles is
22 directly the result of having had the trocar passed
23 through those muscles?

24 A. And deploy the mesh. It's both of those.

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1 It's not one or the other.

2 Q. And have you --

3 A. It's deploying that mesh through those
4 muscles.

5 Q. Okay.

6 A. And the trocar is the way to do it.

7 Q. And have you eliminated Ms. -- Ms. Dimock
8 underwent physical therapy for her levator ani muscles,
9 correct?

10 A. Yes, she did.

11 Q. And in fact she improved, did she not?

12 A. Yes.

13 Q. All right. And have you eliminated her own
14 anxiety and her -- well, as a possible reason for the
15 muscle issues relating to her levator ani pain?

16 A. What I would -- my interpretation of that is
17 that she acquired the complaints with pain and whatever
18 anxiety, if any, she had before would have been
19 exaggerated by virtue of the fact that it has now been
20 almost eight years since she had surgery and six
21 years since her first explant. So it's a reasonable
22 thing to acquire complaints with anxiety if you hurt
23 all the time. So do I think preexisting anxiety made
24 her hurt? No. Do I think she's anxious? I probably

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1 would be too if I had six years of hurting.

2 Q. Well, in connection with your opinions in this
3 case, did you take into consideration any of the
4 personality characteristics of Ms. Dimock relative to
5 anxiety or PTSD or any other psychological condition
6 she's been diagnosed with?

7 A. I'm cognizant of it. PTSD has nothing in the
8 to world to do with the exposed mesh that she has had
9 removed. The operations --

10 Q. How about the anxiety and the pain?

11 A. Well, it may have something to do with being
12 anxious. I don't doubt that. I mean, that's a disorder
13 which I'm not personally familiar with, but it isn't
14 shocking that someone with PTSD would be anxious.

15 Q. Did you take into consideration notes in her
16 file relative to Ms. -- assessment of Ms. Dimock that
17 she needs to be dramatic in order to focus?

18 A. I asked her about that.

19 Q. And what did she say? She denied it?

20 A. No. She didn't deny it. Some people are.

21 Q. Okay. And do you think --

22 A. Some people are dramatic.

23 Q. And do you think some people --

24 A. That doesn't mean that they're going to have

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1 mesh exposed in their vagina. Some people don't say
2 anything.

3 Q. I'm not asking about mesh exposure. We're
4 talking about the pelvic pain and the vaginal pain.

5 A. Right.

6 Q. Do you think that sometimes the issues with
7 respect to anxiety or being dramatic may increase issues
8 with respect to pain in any particular patient?

9 A. Is it possible? If she had no surgery, if she
10 had no product implanted, and she walked in off the
11 street and said that "I hurt," and I found nothing in
12 her surgical history, nothing on physical exam, nothing
13 in her medical history, and she said, "You know, I'm a
14 pretty dramatic person and I need to do that to get
15 attention," but nothing had ever happened to her before,
16 then I would be thinking, well, maybe that's an
17 attention-getting device. I don't think that in this
18 woman. That's not the case with her.

19 She specifically had something done that
20 required deployment of these products in her vagina and
21 whether she had PTSD or any other thing is unrelated to
22 putting a product in her, unless someone knows that
23 people with PTSD shouldn't have these procedures done.

24 Q. Can those diagnoses in any way -- forget the

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1 product --

2 A. Uh-huh.

3 Q. Can they be in any way related to the
4 complaints of pain?

5 A. I suspect without knowing it for a fact that
6 if you or I had PTSD and we were responding to anything
7 under the sun, a nightmare, a dream, a loud noise, it
8 would be different than someone who doesn't have it.
9 So I'm sure it affects how people respond to things.

10 Q. And, now, are you aware that Ms. -- Ms. Dimock
11 told you she had not had sex since before the implant,
12 correct?

13 A. For one year, before.

14 Q. Right. Did you ask her why there were
15 notations in her medical records where she indicated
16 that she was having dyspareunia?

17 A. No. I think that wouldn't be her
18 responsibility. That would have been the person
19 documenting the record's responsibility for entering
20 that, because she was very clear to me and I suspect to
21 everybody else that she didn't have a sexual partner.

22 Q. So Dr. Norton would be wrong if Dr. Norton
23 noted that she was experiencing dyspareunia?

24 A. What the patient could have said --

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1 Q. Well, you know, the question is whether
2 Dr. Norton was wrong.

3 A. Well, if you don't have --

4 MR. CANNON: I'll just object. I think we're
5 getting argumentative.

6 A. Well, what I'll say is I don't know about
7 Dr. Norton's being wrong. What I would say is
8 dyspareunia is pain with intercourse.

9 Q. Okay. How about when Dr. Sharp, did you see
10 the record where he said that Ms. Dimock reported to him
11 that she was having pain with sexual intercourse?

12 A. Well --

13 Q. Would that have been an incorrect record as
14 far as you know?

15 A. Well, what she told me was she hadn't had
16 intercourse since the year before.

17 Q. Okay.

18 A. I wasn't there when she gave a history to
19 Drs. Norton and Sharp, so God only knows what she
20 told them.

21 Q. Did you ask her about whether -- I guess you
22 did ask her, and she said she had not had intercourse,
23 correct?

24 A. Yes.

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1 Q. All right.

2 A. And I didn't -- the time I saw her, I hadn't
3 reviewed all of those records.

4 Q. Okay.

5 A. So that would have required me getting on the
6 phone and saying, "You know, I saw you in November.
7 When did you tell them?" I didn't -- she didn't give
8 me that history.

9 Q. All right. So at the time that you examined
10 her, you had not reviewed any records where there had
11 been a report of dyspareunia; is that what you're
12 saying?

13 A. That's accurate.

14 Q. All right. Ms. Dimock has had some issues
15 with constipation and bowel movements, correct?

16 A. Yes.

17 Q. And did you eliminate those issues as a
18 possible source of any pelvic pain in connection with
19 your opinion that the pain she experiences is strictly
20 related to the Prolift device?

21 A. Well, could she have pain with the
22 constipation? She could. Would she have chronic pain
23 with the physical findings that she has and the history
24 she has and constipation be the primary cause of her

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1 complaint? And the answer is no.

2 Q. Now, Doctor, you are of the opinion that
3 Ms. Dimock would not have experienced the issues she
4 did, specifically mesh erosion and chronic pain, had she
5 had a native tissue repair; is that correct?

6 A. Yes.

7 Q. All right. So with respect to mesh erosion,
8 that's because in a native tissue repair, there is no
9 mesh used, correct?

10 A. That's accurate.

11 Q. All right. Do you have an opinion as to
12 whether -- are you going to express an opinion as to
13 whether a native tissue repair in the case of Ms. Dimock
14 would have been more effective?

15 A. The information that we have about native
16 tissue repairs -- I'll use rectocele. So the information
17 we have about native tissue repair for rectocele,
18 depending on the patient's complaints in advance, the
19 patient could have complaints of a bulge, they could
20 have complaints of inability to empty the distal rectum,
21 they could have complaints of discomfort with
22 intercourse, or they could have no complaints, falls in
23 those four categories.

24 With native tissue surgery, what we know is

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1 seven out of 10 women will have improvement in their
2 bowel function, and nine out of 10 will have reduction
3 of the bulge, not a hundred percent in either one. We
4 know that. We know that some women may have
5 postoperative pain complaints. It is highly unlikely
6 they would be chronic.

7 Q. Okay.

8 A. What we know about mesh products and the
9 posterior vaginal canal for rectocele, there are no
10 reports that indicate improved outcomes in rectocele
11 repair with mesh. None.

12 Q. I understand that. The question I had is:
13 Are you going to issue or render an opinion or testify
14 at trial that, in fact, a native tissue repair in the
15 case of Ms. Dimock would have been more effective than
16 the use of mesh in this particular patient?

17 A. Well, what do you mean by more effective?

18 Q. That there would have been -- the chance of a
19 recurrence would have been -- is higher and was higher,
20 and that if she had had a native tissue repair, the
21 chance of a recurrence would have been lower. Can you
22 say that with any definitive --

23 A. What I can say in her particular circumstance
24 if she had a native tissue repair, she wouldn't have had

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1 these four extra surgeries.

2 Q. I understand the four extra surgeries have to
3 do with the mesh.

4 A. Right.

5 Q. Lysing the mesh arms and the erosion. But the
6 question is efficacy. Would there have been a
7 difference? And you can just say to me, "I'm not going
8 to say that I have an opinion one way or the other as to
9 whether a native tissue repair would have been more
10 effective." I don't care. I just want to make sure I
11 understand what you're going to say.

12 A. What I'm going to say is there is no
13 literature that documents that using a mesh product is
14 better, is more effective. So if there is nothing to
15 say that it's more effective, then what you're left is
16 are they equal, or is one inferior to the other? So
17 could a mesh product be equal in resolving the anatomic
18 abnormality, the bulge?

19 Q. Right.

20 A. They could be equal. One is not better than
21 the other.

22 Q. All right.

23 A. But the issue, if that's all you look at, then
24 you could say the anatomic outcomes may be similar, but

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1 that isn't all we look at.

2 Q. I understand that, but that was my question.

3 So now we'll get to the second question, which is your
4 opinion is had she had a native tissue repair, being
5 an anterior or posterior colporrhaphy --

6 A. Right.

7 Q. -- your opinion is that would have been a
8 safer procedure, because there would be fewer
9 complications, correct?

10 A. That's accurate.

11 Q. All right. Now, I want to make sure that I
12 understand, though. With any surgery, with a native
13 tissue repair, there is a chance or there is a
14 possibility that there can be pelvic pain, correct?

15 A. What I would say is perfect doesn't exist.

16 Q. Right. There is no surgical procedure that's
17 perfect; is that right?

18 A. That's accurate.

19 Q. All right. And with an anterior or posterior
20 colporrhaphy, if there were existing adhesions from some
21 other procedure, that wouldn't make a difference in
22 terms of Ms. Dimock's outcome; is that right?

23 A. Well, I'm going to be a little bit more
24 specific. There could be findings in the vaginal canal,

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1 and that would be very specific to a woman who has had
2 radiation therapy in the vagina. So for some diseases
3 of the pelvis, cancer of the cervix or cancer of the
4 lining of the uterus, some women are treated with
5 radiation in the vagina causing scarring, and there
6 could be problems with vaginal surgery associated with
7 that.

8 When the adhesions are inside the abdomen,
9 which would happen after abdominal hysterectomy or ovary
10 surgery or whatnot, when adhesions are inside the
11 abdomen and the surgery is done through the vaginal
12 canal without entering the abdomen, there shouldn't be
13 anything done vaginally that would be an
14 intra-abdominal problem.

15 Q. And to go back -- strike that.

16 MR. CANNON: Let's go off the record for a
17 second.

18 THE VIDEOGRAPHER: Going off the record. The
19 time is 11:55.

20 (Recess was taken from 11:55 a.m. until 12:02 p.m.)

21 THE VIDEOGRAPHER: Back on the record. The
22 time is 12:02.

23 BY MS. VAN STEENBURGH:

24 Q. Dr. Shull, a couple of follow-up questions.

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1 One, I believe that you testified that they're -- with
2 respect to Ms. Dimock, either the mesh itself
3 contracting or the scar tissue formed around the mesh
4 contracting is a source of Ms. Dimock's chronic pelvic
5 pain, correct?

6 A. That's accurate.

7 Q. All right. And have you looked at literature
8 regarding scarring in connection with the Prolift
9 device?

10 A. Yes, I have.

11 Q. Is there anything different reported in the
12 literature than what you see here with respect to
13 Ms. Dimock?

14 A. You mean on her clinical exam?

15 Q. Right. Either on the clinical exam when you
16 did it or anything in her medical records that would
17 indicate the scarring or adhesions in her particular
18 case are different from what you have seen in the
19 literature relative to the Prolift device?

20 A. My impression is her history is compatible
21 with the chronology of what can happen with patients is
22 that they can have an interval where they're relatively
23 pain free followed by an interval of progressive chronic
24 pain because of these changes in the mesh, the

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1 shrinkage, the contraction, the degradation, the chronic
2 inflammation, so I think her history actually fits what
3 some people are -- in fact do experience.

4 Q. How about the type of scarring here in this
5 particular situation described by Dr. Norton, is that
6 different or is that consistent with what you have seen
7 reported in the literature as to scarring that occurs
8 with a Prolift device?

9 A. It's similar to what I've read about and it's
10 similar to what I have seen personally in revising mesh
11 in patients who have required it.

12 Q. Is it different in some way? You say it's
13 similar, but is there a difference in some way?

14 A. Well, I think every patient is different, so
15 the surgical dissection by her description is tedious,
16 difficult in developing tissue planes between the
17 bladder, the bowel, the vaginal skin, difficulty in
18 exposing the mesh through the scar, so those things are
19 all --

20 Q. So does it sound like it's --

21 A. -- characteristics I've observed when I've
22 done mesh explantation myself, and there are things that
23 are described in the literature that the surgery is
24 technically difficult to do. And that's exactly what

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1 Dr. Norton's note describes. She describes banding,
2 bunching, tissue being taught, difficulty in developing
3 tissue planes, so those are all various characteristics.

4 Q. There is a reference in Dr. Norton's notes to
5 the scarring in this particular case with Ms. Dimock
6 being unusual based upon Dr. Norton's experience. Did
7 you note that?

8 A. Well, I think she probably means it's
9 unusually tedious to take care of it is what she --

10 Q. Well, you don't know what she means, correct?

11 A. No. I would think she means it's unusually
12 difficult to do.

13 Q. Well, in terms of if we are describing the
14 adhesions themselves, would you agree or disagree that
15 they are unusual based upon what is generally reported
16 in the literature?

17 MR. CANNON: I'll object; speculation.

18 A. I don't think I can say that I know that.

19 Q. Okay. And when you say that it's consist with
20 what you have experienced or what you've seen in the
21 literature, you're talking about the difficulty of
22 removing the mesh?

23 A. That's accurate. Identifying it, dissecting
24 it out, and protecting the surrounding structures so you

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1 don't injure the bowel, the bladder, the urethra, the
2 vaginal skin.

3 Q. Okay. Are you're not talking about the actual
4 adhesion constitution itself; is that right?

5 A. That's correct.

6 MS. VAN STEENBURGH: Let's just go off the
7 record for a second. I want to ask Doug something.

8 THE VIDEOGRAPHER: Going off the record. The
9 time is 12:07.

10 (Recess was taken from 12:07 p.m. until 12:09 p.m.)

11 THE VIDEOGRAPHER: Back on the record. The
12 time is 12:09.

13 BY MS. VAN STEENBURGH:

14 Q. Doctor, other than the opinions expressed in
15 your expert witness report and those that you have
16 described today, are there any other opinions that you
17 intend to give at the trial of this matter of
18 Ms. Dimock?

19 A. I'm not aware of it.

20 Q. All right. And have you been asked to
21 supplement your report at all?

22 A. No.

23 MS. VAN STEENBURGH: Okay. And to the extent
24 you do, we will ask for a further deposition on

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1 that. That's all I have. Thank you.

2 THE WITNESS: Thank you.

3 THE VIDEOGRAPHER: This concludes the
4 deposition of Dr. Shull in the Dimock case. Going
5 off the record. The time is 12:09.

6 (The digital recording ended at 12:09 p.m.)

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CERTIFICATE OF REPORTER

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I, Danielle C. Coleman, Stenographic Shorthand Reporter, do hereby certify that I was authorized to and did transcribe the foregoing proceedings from digital recording, and that the transcript, pages 1 through 98, is a true and correct record.

Dated this 15th day of March, 2016.

Danielle C. Coleman

Stenographic Shorthand Reporter